for this amendment is found in the specification on page 6, lines 12-17, and particularly line 15 where it is indicated that dosage within the range applicable to the present invention is without neuroleptic effect in a psychotic patient. The present process is concerned with the anxiolytic process for the treatment of anxiety neuroses, and not the prior art neuroleptic (tranquilizer) process for the treatment of psychoses.

The rejection of all the claims as obvious (35 USC 103) over the two Wu, et al. patents, the Wu, et al. publication, the Allen, et al. publication, and the Sathanathan, et al. publication is respectfully traversed. The Examiner's statement that "Tranquilizers have traditionally been used to treat anxiety conditions." is an over-simplification of the state of the art. The older clinical and experimental literature employed the term "tranquilizer" ambiguously. Webster's Seventh New Collegiate Dictionary (1967) defines tranquilizer as "a drug used to reduce anxiety and tension without impairing mental alertness". Modern medical and psychiatric practice, however, distinguishes between neurotic anxiety and psychotic anxiety and specific definitions for these states have been developed. The Examiner's attention is directed to the definitions quoted in the specification beginning on page 3, line 8, and continuing to the bottom of page 4.

There is no indication in the Wu, et al. patents of any specific disease state for which buspirone is to be employed, there is no implication therein of the outstanding utility of buspirone as an anxiolytic, and there is no invitation in the combination of references to test buspirone for anxiolytic utility.

The Wu, et al. publication and the Allen, et al. publication refer to the psychotropic properties of the buspirone genus and of buspirone specifically as typical of the "major tranquilizers". Refer to the introductory paragraph of each article. In each of these articles, the biological properties of buspirone are reported to be analogous to those of chlorpromazine, the most widely known and used of the so-called "major tranquilizers". Sathanathan, et al. on page 702 in the first full paragraph following Fig. 1, acknowledges the similarity of buspirone to the major tranquilizer chlorpromazine. The cited references are, therefore, believed to be properly interpreted as a teaching of the use of buspirone as an anti-psychotic agent, the modern term for "major tranquilizer", useful for the treatment of psychoses of the sort for which chloropromazine is used chemotherapeutically such as schizophrenia.

For the Examiner's information, copies of several references are enclosed to serve as a glossary of the following terms.

tranquilizer
major tranquilizer
minor tranquilizer
anti-psychotic agent
neuroleptic agent
anxiolytic agent
anti-anxiety agent

The references are listed below.

A. "An Introduction of Psychopharmacology", Rech and Moore, Raven Press, New York (1971), page 261 and page 268.

B. AMA Drug Evaluations, 1st Ed., (1971), page 223, 231, and 232.

C. "The Merck Manual of Diagnosis and Therapy", Berkow and Talbott, 13th Ed., Merck & Co., Inc., Rahway, N.J. (1977), pages 1858, 1859, and 1860.

Reference A, page 261, please refer to the paragraph at the middle of the page immediately following the subtitle; to page 268, the subtitle appearing at the middle of the page and to the first sentence of the following paragraph. These quotations serve to define the terms "neuroleptic agent" and "anxiolytic agent" as synonomous with "major tranquilizer" and "minor tranquilizer", respectively, and to indicate that anxiolytic agents have limited value in the treatment of psychoses.

Reference B, please refer to page 223, left-hand column, first two sentences; to page 223, third paragraph in the left-hand column, last sentence; to page 231, left-hand column, first paragraph, first and last sentences; to page 231, left-hand column, last paragraph, first sentence; and to page 232, left-hand column, third full paragraph. The distinction between anti-anxiety agents and tranquilizers is made and the fact that anti-psychotic agents, although sometimes used to suppress symptoms of anxiety in neurotic patients, are not generally accepted for this use.

Reference C, page 1858, please refer to the heading for the definition of terms and to the latter portion of the second paragraph where it is indicated that phenothiazines, while occasionally used as anti-anxiety agents, are generally unacceptable for this purpose; to page 1859, subtitle near the bottom of the page, for the definition

of terms; and to page 1860, middle of the page, for a listing of commonly used anti-psychotic drugs headed by the phenothiazine, chlorpromazine.

To sum up, the present invention is distinguished from the prior art in that it involves a distinct patient population characterized by a disease state different from that with which the tranquilizer process of the prior art is concerned. By the present amendment, the dose administered in accordance with the claimed process is defined as an anxiolytically effective dose which is neuroleptically ineffective when administered to a psychotic patient. The distinction between the patient populations, psychotic with which the prior art is concerned and neurotic with which this invention is concerned, and the drugs used for their treatment is set out in the specification beginning on page 3, at line 7, and continuing through the first paragraph on page 5. The physical distinction in terms of dosage size between the present process and the prior art is brought out on page 6 at line 7-17. Specific numerical dosage limits art are given in Claims 5 and 8. The dosage range of 10-100 mg./day of the present invention is far removed from the doses of 600-2400 mg./day required to cause remission of symptoms or improvement in clinical status in the treatment of acute schizophrenia (Sathanathan, et al., page 703, third paragraph).

It is submitted that a case for obviousness of the claimed invention has not been made out. The Examiner agrees that the teaching of the Wu, et al. patents with respect to the tranquilizing properties of buspirone is not an anticipation of the present invention since rejection lies under 35 USC 103, and not under 35 USC 102. The

cited journal articles teach that the then known tranquilizing properties of buspirone were antipsychotic properties. The background references cited above as A, B, and C reveal that, while some use of phenothiazine anti-psychotic drugs has been made in the treatment of anxiety neurosis, the latter is distinct from psychosis as a disease entity, and the anti-psychotic drugs have not been accepted by the art as appropriate for the treatment of anxiety neurosis. Even if the cited art were interpreted as suggesting that buspirone be tested as an anti-anxiety agent, the references would not support rejection under 35 USC 103. "Obvious to try" has long been rejected by the Court of Customs and Patent Appeals as a ground for rejection as is reflected in the following opinions.

In re Tomlison, et al., 150 USPQ 623 (CCPA 1966)

In re Dien, 152 USPQ 550 (CCPA 1967)

In re Snoddy, 164 USPQ 299 (CCPA 1970)

In re Antonie, 195 USPQ 6 (CCPA 1977)

In re Goodwin, et al., 198 USPQ 1 (CCPA 1978)

An early allowance of Claim 1-9 is believed to be proper, to be justified by the substantial contribution made by the present inventors, and is respectfully requested.

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Enclosures

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